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IN THE

Supreme Court of the United States

October Term, 1962

No. 643

NATURE FOOD CENTRES, INC., and HENRY K. ROSENBERGER and ANDREW G. ROSENBERGER,
Petitioners.

AGAINST

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

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Petitioners pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the First Circuit, entered in the above-entitled case on November 13, 1962.

Citations to Opinions Below

The opinion of the District Court is printed in Appendix A, *infra*, page 17, and is not officially reported. The opinion of the Court of Appeals is printed in Appendix A, *infra*, page 19, which is not yet officially reported.

Jurisdiction

The judgment of the Court of Appeals was entered on November 13, 1962 (Appendix A, *infra*, p. 25). The jurisdiction of this Court is invoked under 28 U. S. C. 1254(1).

Questions Presented

1. Whether the Court of Appeals was in error in creating two different definitions for the term "labelling", depending upon the section of the Federal Food, Drug and Cosmetic Act in which it appears; where Congress has expressly set forth but one definition.

2. Whether the duality of definition for the term "labelling" created by the Court of Appeals, renders invalid various sections of the Federal Food, Drug and Cosmetic Act because of the resultant vagueness and indefiniteness.

3. Whether the definition for the term "labelling" created by the Court of Appeals is in conflict with the decisions of this Court in *Kordel* v. *United States*, 335 U. S. 345 (1948); *United States* v. *Urbuteit*, 335 U. S. 355 (1948), and *United States* v. *Urbuteit*, 336 U. S. 804 (1949).

4. Whether the standard laid down by the Court of Appeals for compliance with the requirements of Section 502(f)(1) and Regulation 1.106(a)(1), for the statement of conditions of intended use, is correct in a criminal case.

5. Whether the petitioners could be found guilty on all counts of the criminal information even under the standard applied by the Court of Appeals.

Statutes Involved

The statutory provisions involved are Sections 201(k), 201(m), 502(a), 502(d), 502(e), and 502(f)(1) of the Federal Food, Drug and Cosmetic Act [21 U. S. C. 321(k), 321(m), 352(a), 352(d), 352(e) and 352(f)(1)]. Also involved is the Regulation, 21 CFR 1.106(a)(1). They are printed in Appendix B, *infra*, page 26.

Statement

Petitioners are distributors of vitamin products and dietary food supplements throughout the United States. The government prosecuted the petitioners by an information containing thirteen counts.

All of the counts of the information raise in issue one question, as to whether various conditions which were referred to in certain oral lectures are also mentioned or referred to in any of the written or printed material which constitute labelling under the Federal Food, Drug and Cosmetic Act.

No charge has been made in the information that false or misleading claims were made for the products.

The entire case was submitted on a stipulation of facts. The shipments in issue constituted a single shipment in each instance from Boston, Massachusetts to Philadelphia, Pennsylvania or Chicago, Illinois, where part of the shipment was retained in a retail store and the remaining portion went to a lecture hall. It was further stipulated that one of the petitioners lectured for four days in Philadelphia and for four days in Chicago in a lecture hall in each city where the various products in issue were displayed and offered for sale together with the class notes and other literature. It was further stipu-

lated that the lectures were basically taken directly from the class notes.

The government contended that the class notes and other literature do not constitute labelling and further argued, in the alternative, that if the literature did constitute labelling, then five of the thirteen counts would still remain upon the ground that the class notes did not adequately state the conditions of intended use with respect to five of the thirteen counts.[1]

The District Court found the petitioners guilty on all thirteen counts. The District Court ruled that the class notes were labelling and further ruled that the references in the class notes and the lectures were vague, general, and sketchy, and therefore, did not comply with the statute.

The Court of Appeals affirmed the judgment of the District Court but, significantly, ruled completely opposite on the two findings made by the District Court. The Court of Appeals held that the class notes do not constitute labelling, where the question arises under Section 502(f)(1) as distinguished from 502(a) of the Act and further stated that the District Court possibly misspoke itself in its finding that there were vague and general references in both the lectures and the class notes. The completely opposite findings of the District Court and the Court of Appeals is of significance in view of the fact that the entire case was submitted on a stipulation of facts.

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[1] In the District Court, the government admitted in its brief and in oral argument that eight counts would fall if the Court held that the class notes constitute labelling. The government denied that it had made such an admission, in the Court of Appeals, apparently because the District Court held that the class notes were labelling and then disregarded the government's admission in finding the petitioners guilty on all thirteen counts.

The District Court sentenced petitioner, Nature Food Centres, Inc. to pay a fine of $10,000; petitioner, Henry K. Rosenberger was sentenced to be imprisoned for a period of six months, execution of sentence suspended and petitioner placed on probation for a period of two years and to pay a fine of $5,000; and petitioner, Andrew G. Rosenberger was sentenced to be imprisoned for a period of six months, execution of sentence suspended and petitioner placed on probation for a period of two years and to pay a fine of $5,000.

Reasons for Granting the Writ

Petitioners submit that the creation of a duality of definition for the term "labelling", by the Court of Appeals, raises an important question of statutory construction which materially affects the entire Federal Food, Drug and Cosmetic Act. The Court of Appeals has ruled that the word "labelling" changes its definition when it moves from one section to another in the same statute. The term "labelling" is employed in numerous sections throughout the statute in laying down various requirements and creating criminal and civil liabilities. Congress has set forth but one definition for the term "labelling" in this statute. Significantly, Congress has also set forth a definition for the term "label" where Congress has desired to distinguish between two different types of literature, contemplated under the statute. It is respectfully submitted that this new construction of the statute, by the Court of Appeals, should be settled by this Court. Many actions have been brought under the specific section involved in the instant action and the new construction by the Court of Appeals materially affects the entire statute.

Petitioners further urge that the construction set forth by the Court of Appeals is in conflict with the prior decisions of this Court in *Kordel* v. *United States, supra*, and *United States* v. *Urbuteit, supra;* and in conflict with decisions in other cases which have followed the rulings of this Court.

Petitioners respectfully further urge that the new construction created by the Court of Appeals raises an important constitutional question as to whether numerous sections of the statute, as so construed, are rendered invalid for vagueness and indefiniteness. An individual cannot know which definition of the term "labelling" applies in each of the various sections of the statute, so that he cannot know what acts would constitute a criminal violation in each instance, nor what acts of compliance are required under each section.

The petitioners further urge that the construction by the Court of Appeals as to the standard required for compliance with Section 352(f)(1) is erroneous. A very strict and narrow construction of compliance has been applied by the Court of Appeals in imposing criminal liability, in a statute where intent is not an element of the crime.

Settlement of these questions involving both liberty and property is, therefore, in the public interest.

1. The Court of Appeals has ruled that a different kind of "labelling" is required under Section 502(f)(1) of the statute as distinguished from literature which would constitute "labelling" under Section 502(a) of the statute. This construction by the Court of Appeals is erroneous. The Court has, in effect, legislated rather than engaged in judicial construction or interpretation.

Congress has set forth only one definition for the term "labelling" as that term is used in numerous sections

throughout the statute. Section 201(m) of the Federal Food, Drug and Cosmetic Act [21 U. S. C. 321(m)] defines the term "labelling" as written, printed or graphic matter upon any article or "accompanying such article". This Court has heretofore interpreted the term "labelling" with specific reference to the phrase "accompanying such article" in *Kordel* v. *United States, supra*, and *United States* v. *Urbuteit, supra*. In both of these cases, the Court has held that the word "accompanying" as used in the statute does not mean physically present with the product. This Court has held that the controlling factors are whether the literature was designed for use in the distribution and sale of the product and whether it was so used. (See *United States* v. *Urbuteit*, 336 U. S. 804, at page 805 and *Kordel* v. *United States, supra*, at page 350.)

Thus, in *Kordel* v. *United States, supra*, it was held that various literature "accompanied" the products so as to constitute "labelling" under the statute. Some literature was displayed with the products, some literature was sold independently of the drugs, and some literature was mailed to customers by the vendors, including one instance where there was a separation of eighteen months between the shipment of the article and the printed material. This Court held that the fact that some of the booklets carried a selling price was immaterial, as they were part of the distribution program. It is thus apparent that literature constitutes "labelling" under the statutory definition even though there is no physical attachment and even if it is separately offered for sale and thus may never be seen or received by the consumer of the product. Literature will nevertheless constitute labelling where it is designed for use and is used in the distribution and sale of a product. The de-

cisions of this Court have been followed and applied in numerous other cases, including *United States* v. *353 cases* * * * *Mountain Valley Mineral Water*, 247 F. 2d 473 (C. C. A. 8, 1957) and *V. E. Irons, Inc.* v. *United States*, 244 F. 2d 34 (C. C. A. 1, 1957).

It is further significant that Congress has created a definition for the term "label" in Section 201(k) of the Act [21 U. S. C. 321(k)] which means written, printed or graphic material upon the immediate container of the article.

Where Congress wanted certain material to be on the label, present with the product, it so stated, as in Sections 21 U. S. C. 352(d) and (e) [Sections 502(d) and (e) of the Act]. In other sections such as Sections 352(a) and 352(f)(1) [Sections 502(a) and 502(f)(1) of the Act], Congress used the word "labelling" and not the word "label". If Congress had desired to have the information on the label or immediately present with the product as to the information required in 502(f)(1), then Congress would have so stated as it did in the various other sections herein referred to. Congress was very precise in using the word "label" in certain sections and the word "labelling" in others. There are not two different meanings to the word "labelling" in the various sections of the statute.

The Court of Appeals may believe that the requirements of 502(f)(1) should be contained in literature immediately present with the product when offered for sale. This belief or desire, however, cannot be effectuated by judicial interpretation, but is one which would require an amendment by Congress. The change herein attempted by the Court of Appeals is one which is legislative rather than judicial.

Significantly, the charge in the instant case is one of alleged misbranding when the products were introduced into and while in interstate commerce from Boston to Philadelphia and Chicago, respectively. The significance is the omission of any charge of misbranding while held for sale after shipment in interstate commerce. The shipment in each instance constituted a single shipment from Boston destined to Philadelphia or Chicago where part of the shipment was retained in the store and part at the lecture hall. The importance of this fact arises out of the bringing into effect and applying to said shipments the lectures, where the claimed intended uses are drawn from, and the attempt of the government to separate the portion of the shipment which ultimately ended up for sale at the lecture hall. Petitioners are not presently embarking upon a complete discussion of this legal issue. However, it is most significant that it was the very same persons who heard the lectures, and thus the intended uses, to whom were displayed, distributed or available for distribution the class notes and other literature with the products herein.

In the instant case, the class notes and other literature were printed by the petitioners and shipped from Boston to Philadelphia and Chicago. There was a common origin of the products and literature and a common destination of the products and literature at the lectures where the claimed uses were set forth and before the very same persons who heard them.

The literature was designed for use and was used by petitioners in the distribution and sale of the products herein. The literature was displayed with the products and distributed or available for distribution at the lecture halls where the eight specific lectures were given. It is these very lectures which constitute the basis or source of the conditions of intended use.

The criteria laid down by this Court whereby printed matter accompanies an article so as to constitute labelling therefor, are present in the instant case.

2. The Court of Appeals has now stated that the definition of "labelling" in Section 502(f)(1) of the statute is different from the definition of "labelling" in Section 502(a). This duality of definition of the word "labelling" renders numerous sections of the statute void for vagueness and indefiniteness. The word "labelling" and requirements relative thereto appear throughout the statute; with concomitant criminal liability for a failure of compliance.

In view of the decision of the Court of Appeals, we do not know which definition of "labelling" applies in each instance.[2]

A statute which forbids the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning, and differ as to its application, violates the first essential of due process of law.

As this Court said in *United States v. Cardiff*, 344 U. S. 174, 176, holding invalid for indefiniteness Section 704 of the Federal Food, Drug and Cosmetic Act (21 U. S. C. 374):

> "The vice of vagueness in criminal statutes is the treachery they conceal either in determining

[2] See, for example, Section 403(k) which provides that a food shall be deemed to be misbranded unless certain specified information is set forth in the labelling. At this moment we do not know which definition of labelling applies and the problem is further confused when one refers to Section 403(j) which sets forth certain other information which must be upon the *label*. Other sections of the statute which refer to labelling include Section 201(n), 403(a), 403(k), 502(a), 502(f), 505(b), 602(a) and 602(c).

what persons are included or what acts are prohibited. Words which are vague and fluid (Cf. United States v. L. Cohen Grocery Co. 255 U. S. 81, 65 L. ed. 516, 41 S. Ct. 298, 14 ALR 1045) may be as much of a trap for the innocent as the ancient laws of Caligula."

In the instant case, the decision of the Court of Appeals has created vagueness and indefiniteness with respect to numerous acts prohibited under the Federal Food, Drug and Cosmetic Act. The word "labelling" has been changed to a fluid state.

The wrong created by the decision of the Court of Appeals is magnified by the fact that wilfullness is not an element of the crime under the Federal Food, Drug and Cosmetic Act. The penalties of the law may be imposed upon one wholly innocent of knowledge or intent to achieve a purpose proscribed by the statute (*United States* v. *Dotterweich*, 320 U. S. 277).

There would thus appear to be no proper permissible latitude for indefiniteness, herein, where intent to achieve a proscribed purpose is not an element of the crime.

3. The Court of Appeals held that the contents of the class notes fall short of the lectures and thereupon submitted three examples which refer to three counts of the information. Petitioners respectfully submit that even if the strict construction laid down by the Court of Appeals were to be applied in a criminal case, there would still, at a minimum, be eight counts which must be dismissed. The government itself did not question or dispute this fact in the District Court with respect to sixty-one conditions of the seventy-three listed in the information.[3] The sixty-one undisputed conditions would require

[3] See Footnote 1, *supra*.

the aforesaid dismissal of at least eight counts of the information. Illustrative of the fact that the great majority of the conditions are clearly set forth in the class notes and that no question of construction exists, are the following:

a. One of the conditions referred to is that of heart disease and its reference to the Vitamin E (Super E) product. Exhibit 2 (App. 58a) at the bottom of page 4 and top of page 5, clearly states:

> "The value of Vitamin E in heart disease has been demonstrated. * * * the ability of Vitamin E * * * to treat and prevent heart diseases of all types * * *."

There is a further discussion of the use and value of Vitamin E in the treatment of heart disease on those pages and also there may be found a reference to this same fact in Exhibit 1, (App. 56a) at the bottom of page 10 where it states that Vitamin E is needed for a healthy heart.

b. Another claim involved in the information is that relating to healthy skin and Vitamin B (B Amino Complex Product). In Exhibit 1 (App. 56a) page 9, there is a discussion of Vitamin B complex which says that niacin, which is listed under the group of ingredients of the Vitamin B complex "is necessary for healthy skin".

These examples may be multiplied and as previously indicated herein, were not the subject of dispute in the District Court where the government was compelled to concede that if the literature was held to be labelling there could be no question relative to the listing of at least sixty-one of the conditions.

With respect to the three counts involved in the three conditions referred to by the Court of Appeals, petition-

ers respectfully submit that the standard laid down by the Court of Appeals in a criminal case for such compliance is too strict and too narrow to support a criminal conviction.

Thus, the Court of Appeals states that the lecture discussed the restoration of the original color of the hair by the use of petitioners' Vitamin B product called Hemo-Glo. In the class notes, Vitamin B complex, is discussed as helping to prevent graying of hair and in retaining normal hair coloring. The Court draws a very fine line of distinction between the words retaining normal hair coloring, preventing graying of the hair and restoring original color.

The Court also discusses the loss of smell referred to in Count Five of the information. The lecture which discusses the loss of smell clearly states in Exhibit 20, at the bottom of page 7 (App. 91a):

> "Lost part of hearing and smell after a very bad cold * * *."

The loss of smell was thus discussed as a symptom related to a cold or caused by a cold. In the class notes, petitioner discussed this subject in Exhibit 3a (App. 60a) on pages 53 and 54, and also sets forth further discussion of this kind in Exhibit 2 (App. 58a) beginning on page 21 which discusses the entire question of colds and the prevention of colds. The statement of conditions most certainly should not be one of isolating a single word out of context from a complete discussion of a subject. In both instances, we have a discussion of colds and the reference carefully extracted by the Court is as to a symptom which the lecture clearly referred to as relating to or being caused by a cold. Were we to carry forward and apply the standard laid down by the Court of Ap-

peals, we could find a variance, and thus a criminal violation of the statute, if in one place the petitioner said that you could treat colds and discussed somewhere in his statement having had *sniffles* when he had a cold, whereas, in the other literature he merely discussed colds without the one word *sniffles*.

It is submitted that the purpose and intent of the statute is not to ensnare and trap the businessman for failure to repeat a word or phrase. The statute requires a statement of the conditions for use of the product and compliance should not require fine lines of language interpretations.[4]

The statute and regulations require that there be a statement of the conditions of intended use. It is thus apparent that the question involves two factors. The first factor is the source of the intended use which, in the present case, is the lectures, and the second factor is the labelling material which, in the instant case, is the class notes and other circulars. Petitioners submit that there has been compliance with the statutory requirements. The conditions of use which are discussed in the lectures are set forth in the literature. Significantly, it was even stipulated between the parties, in paragraph numbered 54 of the stipulation of facts, that the material for the lectures was "basically taken directly from the class notes" (App. 44a). This stipulation of fact is particularly relevant in a criminal case where the government must prove its charges beyond a reasonable doubt and must thus prove a variance between the lectures and the class notes which is one of substance and not microscopic differences.

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[4] With respect to the reference to lung conditions, the Court of Appeals apparently overlooked the statement in Exhibit 3a (App. 60a) Page 12 which refers to the lungs and the accumulation of extracellular fluids in the lungs in the second paragraph from the bottom of that page.

Petitioners respectfully submit that this Court should rule upon and settle this question as to the standard of compliance required, in a criminal action, under Section 502(f)(1) of the statute.

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

Respectfully submitted,

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Dated: December 6, 1962.